CLAIMS:

1. An assay for determining rapamycin or rapamycin analog concentrations in a sample comprising:

(i) contacting the sample with PKBP12 protein, or with a rapamycin binding fragment of said PKBP12 protein that maintains the rapamycin binding properties, for a time period and under conditions allowing formation of rapamycin/FKBP12 complex;

(ii) contacting the rapamycin/FKBP12 complex with a complex-binding domain of mTOR for a time period and under conditions enabling binding of the complex to said complex-binding domain;

(iii) detecting the amounts of said complex-binding domain that is bound to the rapamycin/FKBP12 complex ;

(iv) comparing the amounts detected in (iii) to a calibration curve, thereby determining the rapamycin concentrations in the sample.

2. The assay of claim 1, wherein said rapamycin being native rapamycin or synthetically produced rapamycin, or any analog of the two.

3. The assay of claim 1, wherein said sample is a liquid, a solid or a semi solid sample.

4. The assay of claim 3, wherein said liquid sample is a body fluid selected from plasma, blood, serum, urine, sperm, or cerebral spinal fluid.

5. The Assay of claim 3, wherein said solid sample is a tissue.

6. The assay of claim 3, wherein said sample is semi-solid sample selected from tissues or feces.

7. The assay according to claim 4, wherein said liquid sample is mammalian blood.

8. The assay according to claim 1, wherein said FKBP12 protein is full FKBP12 protein being a 12kDa protein or a fragment of FKBP12 protein that maintains the rapamycin binding properties of the full protein.

9. The assay according to claim 1, wherein the FKBP12 protein or the fragment thereof is immobilized on a solid substrate.

10. The assay according to claim 9, wherein said solid support is a 96-well microtiter plate.

11. The assay according to claim 10, wherein said microtiter plate is blocked by non specific protein.

12. The assay according to claim 1, wherein said detection is achieved by an ELISA reader.

13. The assay of claim 1, wherein said complex binding domain of mTOR is a FRB fragment.

14. The assay according to claim 13, wherein said FRB fragment is directly bound to a detectable label.

15. The assay according to claim 13, wherein said FRB fragment is indirectly bound to a detectable label.

16. The assay according to claim 14 or 15, wherein said label is capable of generating a signal detectable by a technique selected from coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry or radiospectrometry.

17. The assay according to claim 16, wherein said detectable label is an enzyme capable of producing, in the presence of a suitable substrate, a color reaction.

18. The assay according to claim 17, wherein said enzyme is alkaline phosphatase or HRP enzyme.

19. The assay according to claim 18, wherein said enzyme is used with a color-forming reagent or reagents selected from p-nitrophenyl phosphate, hydrogen peroxide, o-phenylenediamine and 3,3′,5,5′-Tetramethylbenzidine.

20. A kit for determining rapamycin concentrations, or rapamycin analog concentrations in a sample, the kit comprising:

(i) PKBP12 protein or a rapamycin binding portion thereof immobilized on a solid substrate; and

(ii) a complex-binding domain of mTOR linked to a label that may be detected or that may generate a signal.

21. The kit of claim 20, wherein said complex binding domain of mTOR is provided in separate vessel.

22. The kit according to claim 20, wherein said complex binding domain of mTOR is the 93-amino acids FRB domain, linked to a label that can be detected or that can generate a signal.

23. The kit according to claim 22, wherein said label is capable of generating a signal detectable by a technique selected from coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry or radiospectrometry.

24. The kit according to claim 22, wherein said label is capable of producing a colorimetric reaction.

25. The kit according to claim 22, wherein said label is an enzyme capable of producing, in the presence of a suitable substrate, a colorimetric reaction.

26. The kit according to claim 25, wherein said enzyme is alkaline phosphatase enzyme or HRP enzyme.

27. The kit according to claim 22 further comprising antibodies which are conjugated to an enzyme capable of producing a colorimetric reaction.

28. The kit according to claim 27, wherein said antibodies are directed against the FRB fragment.

29. The kit according to claim 24, wherein said antibodies are directed against a tag to which FRB or FRB fragment are being conjugated.

30. The kit according to claim 22 further comprises the label required to generate a signal detectable by a technique selected from coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry or radiospectrometry.

31. The kit according to claim 22 further comprising pre-weighed samples of rapamycin and rapamycin analogs for producing calibration curves.